



10-21-04

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Express Mail No. EV 475 141 100 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Dasseux *et al.*

Confirmation No.: 9582

Serial No.: 10/743,950

Art Unit: 1642

Filed: December 24, 2003

Examiner: To be assigned

For: SULFIDE AND DISULFIDE
COMPOUNDS AND COMPOSITIONS
FOR CHOLESTEROL
MANAGEMENT AND RELATED
USES

Attorney Docket No: 10173-112-999
(CAM #371855-999107)

PETITION UNDER 37 C.F.R. §§ 1.181 AND 1.17(h) IN
RESPONSE TO NOTICE OF OMITTED ITEM(S) IN A
NONPROVISIONAL APPLICATION AND EVIDENCE OF DEPOSIT

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Petition is in response to the Notice of Omitted Item(s) in a Nonprovisional Application (the "Notice"), mailed in connection with the above-identified application on September 13, 2004. Applicants hereby petition the Commissioner to maintain the original filing date of December 24, 2003 for the above-identified patent application. The reasons supporting this petition are set forth below in the "Remarks" section. Applicants submit herewith: (1) a copy of the Notice; (2) a copy of the return-receipt postcard (both sides) date-stamped "DEC 24 2003" by the United States Patent and Trademark Office (the "USPTO") in connection with the filing of the above-identified application; (3) a copy of page 1 of the above-identified application as filed; (4) a copy of page 125 of the above-identified application; and (5) a copy of U. S. Patent No. 6,703,422, to which the present application claims priority under 35 U.S.C. § 120.

10/22/2004 YPOLITE2 00000007 503013 10743950

01 FC:1460 130.00 DA

REMARKS

The Notice states that page 125 is missing from the present application. Applicants submit herewith a return-receipt postcard date-stamped "DEC 24 2003" indicating receipt of 246 pages (*i.e.*, 245 pages of specification and 1 page abstract) of the above-identified application by the USPTO. Thus, based upon the enclosed return-receipt postcard, Applicants petition to have page 125 entered into the file of the above-identified application and to have the original filing date of December 24, 2003 maintained. A copy of page 125 is enclosed herein to complete the USPTO's records.

In the alternative, applicants petition the USPTO to maintain the original filing date of December 24, 2003 of the above-identified application on the basis that the submission of page 125 even at this time would not constitute new matter. More specifically, the present application is a continuation-in-part of United States Patent Application Serial No. 09/976,898 (the "'898 application"), which is now United States Patent No. 6,703,422 (the "'422 patent") to Dasseux *et al.* and incorporates by reference the '898 application in its entirety (see page 1 of the above-identified application as filed which is enclosed herewith).

The '898 application as filed (as well as the '422 patent as issued) contain the subject matter of page 125. Page 125 sets forth five compounds (IIIa-9, IIIa-10, IIIa-11, IIIa-12 and IIIa-13) which are set forth in the '422 patent (a copy enclosed) as issued at columns 105-106, 2nd-6th compounds. Therefore, since the present application, as filed, contained page 125 at least by reference, submission of page 125 even at this time does not constitute new matter. Therefore, applicants petition that page 125 be entered into the file of the above-identified application and that the application be accorded its original filing date of December 24, 2003 in view of the return-receipt postcard indicating receipt of all 246 pages of the application by the USPTO or, in the alternative, in view of the fact that page 125 was incorporated by reference into the above-identified application at the time of filing.

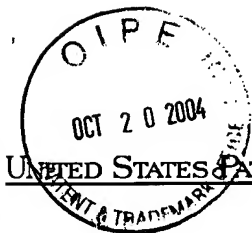
Pursuant to 37 C.F.R. § 1.17(h), it is estimated that the fee for filing this Petition is \$130.00. Please charge the required fee to Jones Day Deposit Account No. 50-3013. A duplicate copy of this Petition is enclosed.

Date: October 20, 2004

Respectfully submitted,

By: Anthony M. Insogna, Reg. No. 35,203
Michael J. Bruner, Reg. No. 47,458
By: Michael J. Bruner (Reg. No. 47,458)
For: Anthony M. Insogna (Reg. No. 35,203)
JONES DAY
222 East 41st Street
New York, New York 10017
(858) 314-1130

Enclosures



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

| APPLICATION NUMBER | FILING OR 371 (c) DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NUMBER |
|--------------------|------------------------|--------------------------|------------------------|
| 10/743,950 | 12/24/2003 | Jean-Louis Henri Dasseux | 10173-112-999 |

20583
 JONES DAY
 222 EAST 41ST ST
 NEW YORK, NY 10017

CONFIRMATION NO. 9582
FORMALITIES LETTER
OC000000013782535
OC000000013782535

Date Mailed: 09/13/2004

NOTICE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

A filing date has been accorded to the above-identified nonprovisional application papers; however, the following item(s) appear to have been omitted from the application:

- Page(s) **125** of the specification (description and claims).

I. Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and \$130.00 petition fee (37 CFR 1.17(h))) with evidence of such deposit **must** be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if it is determined that the item(s) was received by the USPTO.

II. Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s) (with a supplemental oath or declaration in compliance with 37 CFR 1.63 and 1.64 referring to such items), and a petition under 37 CFR 1.182 (with the \$130.00 petition fee (37 CFR 1.17(h))) requesting the later filing date **must** be filed within **TWO MONTHS** of the date of this Notice.

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(e)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted item(s) and the petition (and petition fee) requesting the later filing date.

III. The failure to file a petition (and petition fee) under the above options (I) or (II) within **TWO MONTHS** of the date of this Notice (37 CFR 1.181(f)) will be treated as a constructive acceptance by the applicant of the application as deposited in the USPTO. **THIS TWO MONTH PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136(a) or (b).** In the absence of a timely filed petition in reply to this Notice, the application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (*i.e.*, the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit.

In the event that applicant elects not to take action pursuant to options (I) or (II) above (thereby constructively electing option (III)), amendment of the specification to renumber the pages consecutively and cancel incomplete sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the

references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes. Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

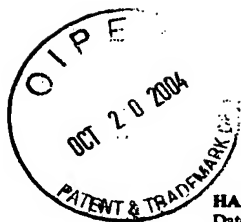
*A copy of this notice **MUST** be returned with the reply.*

WAT -

Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

**HAND CARRY**

Date Mailed December 24, 2003
Serial No. CIP of Application No. 09/976,898 filed on October 11, 2001
Inventor DASSEUX et al.
For SULFIDE AND DISULFIDE COMPOUNDS AND COMPOSITIONS FOR CHOLESTEROL
MANAGEMENT AND RELATED USES

Filed December 24, 2003

- | | |
|----------------------------------------------------------------------|------------------------------------------------------------------------|
| <input type="checkbox"/> Affidavit/Declaration | <input type="checkbox"/> Fee Address Indication Form |
| <input type="checkbox"/> Amendment (Preliminary) | <input checked="" type="checkbox"/> Fee Calculation |
| <input checked="" type="checkbox"/> Application, 246 pages | <input type="checkbox"/> Issue Fee Transmittal & Publication Fee (dup) |
| <input checked="" type="checkbox"/> 57 Claims 5 Drawing Sheets | <input type="checkbox"/> Letter |
| <input type="checkbox"/> Appeal, Notice of | <input type="checkbox"/> Oral Hearing Request/Confirm |
| <input type="checkbox"/> Assignment w/ Notice of Recordation Sheet | <input type="checkbox"/> Petition to Extend Time (dup) |
| <input checked="" type="checkbox"/> Declaration (Unexecuted) | <input type="checkbox"/> Power of Attorney |
| <input type="checkbox"/> Design Application | <input type="checkbox"/> Associate Power w/Revocation |
| <input type="checkbox"/> Disclaimer | <input type="checkbox"/> Sequence Listing w/ Computer |
| <input type="checkbox"/> Disclaimer | Readable and Paper Copy |
| <input type="checkbox"/> Disclosure Statement (Form PTO-1449) | <input type="checkbox"/> Small Entity Statement |
| <input type="checkbox"/> w. refs. <input type="checkbox"/> w/o refs. | <input checked="" type="checkbox"/> Transmittal Letter |
| sheets | <input checked="" type="checkbox"/> Fee By Deposit Account No. 16-1150 |

Other:

File no.: 10173-112-999

Sender: AML/DXF/kym



File No. _____ Sender _____



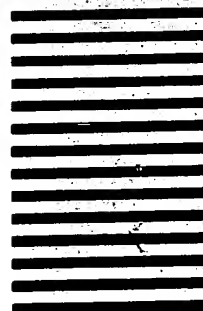
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in the U.S.

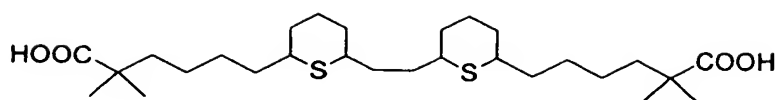
BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 1825 NEW YORK, NY

POSTAGE WILL BE PAID BY ADDRESSEE

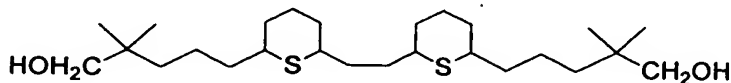
Pennie & Edmonds LLP
1155 Avenue of the Americas
New York, NY 10109-1441





IIIa-9

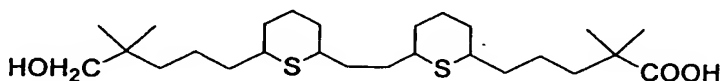
5 6-(6-{2-[6-(5-Carboxy-5-methyl-hexyl)-tetrahydro-thiopyran-2-yl]-ethyl}-tetrahydro-thiopyran-2-yl)-2,2-dimethyl-hexanoic acid



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IIIa-10

5-(6-{2-[6-(5-Hydroxy-4,4-dimethyl-pentyl)-tetrahydro-thiopyran-2-yl]-ethyl}-tetrahydro-thiopyran-2-yl)-2,2-dimethyl-pentan-1-ol

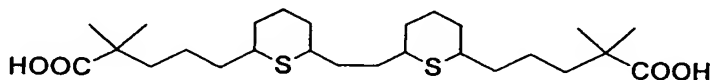


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IIIa-11

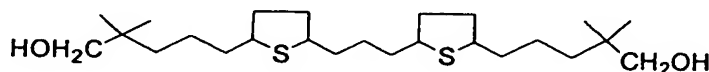
5-(6-{2-[6-(5-Hydroxy-4,4-dimethyl-pentyl)-tetrahydro-thiopyran-2-yl]-ethyl}-tetrahydro-thiopyran-2-yl)-2,2-dimethyl-pentanoic acid

20



IIIa-12

25 5-(6-{2-[6-(4-Carboxy-4-methyl-pentyl)-tetrahydro-thiopyran-2-yl]-ethyl}-tetrahydro-thiopyran-2-yl)-2,2-dimethyl-pentanoic acid



30

IIIa-13

5-(5-{3-[5-(5-Hydroxy-4,4-dimethyl-pentyl)-tetrahydro-thiophen-2-yl]-propyl}-tetrahydro-thiophen-2-yl)-2,2-dimethyl-pentan-1-ol

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SULFIDE AND DISULFIDE COMPOUNDS AND COMPOSITIONS FOR CHOLESTEROL MANAGEMENT AND RELATED USES

This application is a continuation-in-part application of pending U.S. Application No. 09/976,898, filed October 11, 2001, which is incorporated herein by reference in its entirety.

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1. Field of The Invention

The present invention relates to sulfide and disulfide compounds and pharmaceutically acceptable salts, hydrates, solvates, or mixtures thereof; compositions comprising a sulfoxide or bis-sulfoxide compound or a pharmaceutically acceptable salt, hydrate, solvate, or a mixture thereof; and methods for treating or preventing a disease or disorder such as, but not limited to, aging, Alzheimer's Disease, cancer, cardiovascular disease, diabetic nephropathy, diabetic retinopathy, a disorder of glucose metabolism, dyslipidemia, dyslipoproteinemia, enhancing bile production, enhancing reverse lipid transport, hypertension, impotence, inflammation, insulin resistance, lipid elimination in bile, modulating C reactive protein, obesity, oxysterol elimination in bile, pancreatitis, Parkinson's disease, a peroxisome proliferator activated receptor-associated disorder, phospholipid elimination in bile, renal disease, septicemia, metabolic syndrome disorders (e.g., Syndrome X), and a thrombotic disorder, which method comprise administering a sulfide or bis-sulfide compound or composition of the invention. The compounds of the invention can also treat or prevent inflammatory processes and diseases like gastrointestinal disease, irritable bowel syndrome (IBS), inflammatory bowel disease (e.g., Crohn's Disease, ulcerative colitis), arthritis (e.g., rheumatoid arthritis, osteoarthritis), autoimmune disease (e.g., systemic lupus erythematosus), scleroderma, ankylosing spondylitis, gout and pseudogout, muscle pain: polymyositis/polymyalgia rheumatica/fibrositis; infection and arthritis, juvenile rheumatoid arthritis, tendonitis, bursitis and other soft tissue rheumatism.

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2. Background of The Invention

Obesity, hyperlipidemia, and diabetes have been shown to play a causal role in atherosclerotic cardiovascular diseases, which currently account for a considerable proportion of morbidity in Western society. Further, one human disease, termed "Syndrome X" or "Metabolic Syndrome", is manifested by defective glucose metabolism (insulin resistance), elevated blood pressure (hypertension), and a blood lipid imbalance (dyslipidemia). See e.g. Reaven, 1993, *Annu. Rev. Med.* 44:121-131.